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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,891	01/05/2004	Holger Puchta	532622003100	2084
7590	07/17/2006			EXAMINER
Roberte M. D. Makowski Connolly Bove Lodge & Hutz LLP 1007 North Orange Street P.O. Box 2207 Wilmington, DE 19899			ZHENG, LI	
			ART UNIT	PAPER NUMBER
			1638	
			DATE MAILED: 07/17/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/750,891	PUCHTA ET AL.	
	Examiner Li Zheng	Art Unit 1638	

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 April 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 5-30 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 05 January 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/2005</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-4, amendment to the claims 4-5, 11, 13 and 15, as well as addition of new claims 27-30 in the reply filed on 4/24/2006 are acknowledged. Applicants also elected "selection marker" for the element. Non-elected subject matter should be removed from the claims. The newly added claims 27-30 belong to non-elected group VII. The traversal is on the ground(s) that all claims are related, restriction to only claims reciting one element or one enzyme is inappropriate (response, page 9, last two paragraphs) and that the search and examination of all groups of claims do not present an undue burden (response, page 10, lines 5-13). The examiner maintains that the patentable distinctness among all groups are well established. The existence of linking claims alone does not prevent examiner from requiring restriction among elements and enzymes. The examiner maintains that the search and examining of all groups is undue, as each group requires searching for different construct components and analysis of unrelated literature.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The disclosure is objected to because of the following informalities:

Figure 7 contains multiple views that are labeled with a letter. However, the brief description of the figure in the specification does not recite those labels. The brief description should be amended to recite those labels. See 37 CFR 1.74.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1: the recitations, "sufficient length" and "sufficient homology" render the claim indefinite. The recitations are relative terms, having no definite meaning. The definition on page 10 of specification is unclear due to the recitation "preferably" which itself has no definite meaning. The metes and bounds of the claim are unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Lyznik et al. (1996, *Nucleic Acids Research* 24:3784-3789).

Lyznik et al. teach a recombination system comprising a binary vector for plant transformation comprising in a 5'- to 3' orientation an intron sequence of *Ubi-1* gene (homology sequence A), a selection marker, *neo* gene, a recognition sequence for site-directed induction of DNA double-strand breaks (FRTm site), an said intron (homology sequence B) and a FRT site as well as another vector comprising a nucleotide sequence encoding FLP recombinase (the enzyme that makes double strand break at FRT and FRTm sites) (see Figure 1). The reference meets all the limitation set forth by claims 1-4.

5. Claim 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Dujon et al. (U.S. Patent No. 6,395,959 filed in 1996).

Dujon et al. teach that a recombination system comprising a vector comprising from 5' to 3' a LTR sequence, a I-SceI type II restriction enzyme recognition site as a recognition sequence for site-directed induction of DNA double-strand breaks, a Phleomycin selection marker, another LTR sequence and I-SceI type II restriction enzyme recognition site, as well as a second viral vector expressing I-SceI type II

restriction enzyme (Figures 20A-E). The two LTR sequences meet the structural limitations for homology sequence A and B of the instant claims. The reference thus meets all the limitation set forth by claims 1-4.

Conclusion

Claims 1-4 are rejected.

Claim 4 is objected to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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PRIMARY EXAMINER